Special 510(k) Summary

K103152

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Esaote S.p.A. Via Siffredi 58 Genoa, Italy 16153

Contact Person:

Allison Scott

317.569.9500 x106

ascott@ansongroup.com

Date:

October 22, 2010

807.92(a)(2)

Trade Name:

6250 System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse Doppler imaging system 892.1550

Ultrasonic pulsed echo imaging system 892.1560

Classification Number:

90IYN; 90IYO; 90ITX

807.92(a)(3)

Predicate Device(s)

K051308, K052805, K060827, K081386 and K091009

6150

Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 6150 is a mainframe ultrasound system, used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The system is equipped with a LCD Color Display, a control panel and is capable of operating Linear, Convex, and Phased array probes.

The 6150 system has been cleared by FDA via K051308, K052805, K060827, K081386 and K091009.

The modified 6150, with respect to the cleared version 6150 via K051308, K052805, K060827, K081386 and K091009, is due to the improvements of the system. These modifications, that do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- a. New keyboard (control panel), where some control keys (knobs and keys) have been replaced by a touch screen.
- b. New plastic housing of the system both to include the touch screen and to give a new style
- c. New keyboard group PCBs lay out to interface the touch screen and to match the new organization of the panel keys.
- d. Software/Firmware modification to translate the touch screen information for the software: main software characteristics and performances have not been changed.

The 6250 is the model name of the modified 6150. The set of probes of the 6150 and the 6250 is exactly the same.

The 6250 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general / ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Special 510(k) Summary 6250 System Esaote, S.p.A.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

Technological Characteristics

The modifications reflected in this Special 510(k) for the 6250 are intended to improve the system's performance. The modifications have not altered the fundamental scientific technology or the intended use of the unmodified version of the 6150 cleared via K051308, K052805, K060827, K081386 and K091009.

Esaote, S.p.A. 6250 Special 510(k) Page 13 of 1219



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Esaote S.p.A. % Ms. Allison Scott, RAC Regulatory Associate Anson Group 11460 N. Meridian Street, Suite 150 CARMEL IN 46032

JAN - 7 2011

Re: K103152

Trade/Device Name: 6250 Ultrasound Systems

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: October 22, 2010 Received: October 26, 2010

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 6250 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

	•		
PA230	<u>LA532</u>	<u>CA631</u>	<u>TEE022</u>
PA122	LA932	<u>2CW</u>	<u>TEE022</u>
PA023	C5-2R13	<u>5CW</u>	<u>IOE323</u>
PA240	CA123	HF CW	<u>LP323</u>
LA332	CA421	EC123	<u>BC431</u>
LA435	CA621	EC1123.	<u>BL433</u>
LA522	CA430	EC1123	
LA523	CA431	BE1123	2 · · · · · · · · · · · · · · · · · · ·
	===10=		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,

David G. Brown, Ph.D.

Acting Director

Division of Radiological Devices Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Model 6250

JAN - 7 2011

Indications for Use

K103152

510(k) Number (if known):

Device Name:

6250 Ultrasound Systems

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K103152

						Mode of	Mode of Operations			
Ciinical Application	8	Σ	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined 4	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (apecify)
Ophthalmic			L							
Petal	۵.	a	_	•	a.			a	۵	5, 6, 7, 8, 12, 13
Abdominal	اه	d		۵	۵	۵.		•	4	5, 6, 7, 8, 12, 13
intraoperative (Abdominal)	•		۵.		۵	۵	۵	•	s.	5, 6, 8, 12, 13
Intraoperative Neurological										
Pediatric	4	۵	•	_	4	А	4	Ь	a	5, 6, 7, 8, 12, 13
Small Organ [1]	d	_	_	_	۵	_	۵	<u>a</u>	a	5, 6, 7, 8, 12, 13, 14
Neonatal Cephalic	d	L	•	_			4	4		5, 6, 8, 12
Adult Cephalic	d	Ь	٩	4	ß,	٩	_			5, 6, 7, 8, 12
Cardiac [2]	d	d	ď	a.	a,	۵	a.	a,	P (15)	5, 6, 7, 8, 10, 11, 12
Transesophageal (Cardiac)	4	Ы	d	d	p.	Ь	1	d	۵	5, 6, 8, 10, 11, 12
Transcsophageal (Non Cardiac)										
Transfectal	_	L	۵		_	۵	_	<u>a</u>	4	5, 6, 7, 8, 12, 13, 14
Transvaginat	Ь	ď	۵		۵.	a		4	•	5, 6, 7, 8, 12, 13
Transurethral										
Intravascular										
Peripheral Vascular	•	_	_	۵		_		-	۵	5, 6, 7, 8, 12, 13
Laparoscopic	d		۵		_	_				
Musculo-skeletal Conventional	d.	۵	a.	۵.	e.	<u>.</u>	a.	la.	۵	5, 6, 7, 8, 12, 13, 14
Musculo-skeletal Superficial (3)	ф	4	a.	۵.	۵.	۵	2.	ı	a.	5, 6, 7, 8, 12, 13, 14
Other (Urological)	d	Ь	a	4	۵	a		<u>-</u>	۵	5, 6, 7, 8, 12, 13
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N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Teaticles

[2] Cardiac is Adult and Pediatno

[3] Musculo Skeletal - Nerve Block

|4| Combined modes are: B+M+PW+CW+CPM+PD

|5| Compass M-Mode (CMM) |6| 3D |7| 4D |8| Vpan |9| XView

(10) Stress

(Diffusion Sign-Off)
Division of Radiological Devices
Office of in Vitro Diagnostic Device Evaluation and Safety

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[11] Xstrain

[12] Compound Imaging (Mview)
[13] Trapezoidal View (FP-View)
[14] Elasapezoidal View (FP-View)
[14] Elasapezophy
[15] Inchides contrast (Crit) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k051308, k052805, k060827, k081385 and k091009

						Mode of Operations	erations			
Clinical Application	m.	M	PWD	смр	Color Doppler	Amplitude Combined Doppler [4] (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										t
Fetal	4	4	4	_	۵	۵	4		4	5, 6, 9
Abdominal	Δ,	d	Ь	_	_	۵	Δ,	a.	a.	5, 6, 9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	ρ.	α,	Д	4	۵.	ц	a.		۵	5, 6, 9
Small Organ [1]	а.	۵.	٩	Δ.	4.	ď			a,	5,6,9
Neonatal Cephalic										
Adult Cephalic	d	d	4	Ь	d.	a	4	ы	-	5,6,9
Cardiac [2]	d	d	d	d.	d.	a.	Д	d,	P (16)	5, 6, 9, 10, 11
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular							ļ -			
Peripheral Vascular	d	4	Ъ	4	Д	a.	_	٦	Ь	5,6,9
Laparoscopic										
Musculo-skeletal Conventional							İ			
Musculo-skeletal Superficial [3]										
Other [Urological]										
N: New indication; P: Previously cleated by FDA; E:Added under Appendix E	lenred by F	DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compass M-Mode [CMM]

(6|3D

[9] XView [10] Stress

[11] Xstrain

[16] Includes contrast (CnTl) in Adult Cardiac for left ventricle apacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

						Mode of Operations	erations			
Clinical Application	В	×	DWD.	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other (specify)
	_				Doppler	Doppler (PD)	<u>∓</u>	Mapping (FVM)	Imaging (TEI)	
Ophthalmic										
Fetal										
Abdominal	ď	۵.	đ	ā	_	Α.			d	5,6,9
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ь	d	d	a,		۱۵.	4		А	5, 6, 9
Small Organ [1]										
Neonatal Cephalic	d	۵	۵.	ь.	_	۵	d		ф	5,6,9
Adult Cephalic										
Cardiac [2]	Ь	ď	<u>-</u>	а	4	Ь	-	Ь	d	5, 6, 9, 10, 11
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	b	Ь	Ь	c.	۵	ı	ď		d	5, 6, 9
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N: New indication; P. Previously cleared by FDA; E:Added under Appendix E	leared by 1	FDA: E:Add	led under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

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|4| Combined modes are: B+M+PW+CW+CFM+PD [5] Compass M-Mode (CMM)

[6] 3D [9] XView [10] Stress [11] Xstrain

Previously cleared via k100931

Ctinical Application B M Ophthalmic Fetal Abdominal Intraoperative (Abdominal) Intraoperative Neurological Pediatron Small Organ 111 Neurol Christian Neurol Christian Neurol Christian Neurol Christian Neurol Christian Ne	PWD		Calor Dopplet	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping [TVM]	Harmonic Imaging (TEI	Other [specify]
Abdominal teurological P	Δ. α.							
Abdominal leurological P	à. a.							
Abdominal) leurological P	<u>a.</u>	<u> </u>						
Abdominal) leurological P	à, a.	<u> </u>	<u>.</u>					
leurological P	à. a.	<u>a</u>]	G.					
a	۵. c.	٠	<u>.</u>					
	α,			-	۵		d	5, 6, 9
	d,	,						
		ı	<u>a</u>	_	4		۵	5,6,9
Adult Cephalic								
Cardiac [2] P P	d	ф	d		۵		۵	5, 6, 9, 10, 11
Transesophageal (Cardiac)		_						}
Transenophageal (Non Cardiac)								:
[ransrecta]								
Transvaginal		l						
Transurethral		H						
ntravascular		_						
Peripheral Vascular P P	_	_	_	_	_		۵	5,6,9
Laparoscopic								
Musculo-akeletal Conventional					i			
Musculo-skeletal Superficial [3]	· · · · · · · · · · · · · · · · · · ·							
Other (Urological)		-						

N: New indication; P: Premously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

| H | Combined modes are: | B+M+PW+CW+CW+PD | S | Compass M-Mode (CMM) | G | 3D | 9 | XView | 10 | Siress | 11 | Xstrain

Previously cleared via k100931

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Ophthatmic Purple Purple Cup Cup				!			Mode of Operations	rations			
	Clinical Application	B	×	PWD	CWD	Color Doppler	Amphtude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
	Ophthalmic										
	Fetal	1	_		_	a.	ā	Ŀ		ф	5, 5, 9
	Abdominal	-	-	4	-	â		1		-	5,6,4
	Intraoperative (Abdomina))										
	intraoperative Neurological										
	Pediatric	_		_		_	1	-		_	5,6,0
	Smell Organ [1]	-	å	a.	_	۵	۵	_		۵	5, 7, 9
	Neonatal Cephalic								-		
	Adult Cephalic	٦	a.	ď	п.	۵	А	a			5, 6, 9
	Cardiac [2]	-	_	à,	٦	_	-	-	_	P (16)	5, 6, 9, 10, 11
	Transesophageal (Cardiac)										
	Transesophageal (Non Cardiac)										
	Transcectal					İ					
	Transvaginal										
	Transurethral										
	Intravascular										
Lapazoteopic Musculo-skeletal Conventional Musculo-skeletal Superficial [3]	Peripheral Vasculas		_	1	-	_	_	-		<u>-</u>	5, 11, 9
Musculo-sketeral Conventional (3) Musculo-sketeral Superficial (3)	napa o seconic										
Musculo-akeletal Superficial [3]	Musculo-skeletal Conventional										
	Musculo-skeletal Superficial [3]							ĺ			
Other (Urological)	Other (Urological)										

N: New indication; P. Previously cleared by FDA; E.Added under Appendix E.

[1] Sinall Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

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|5| Compass M-Mode (CMM) |6| 31) |9| XVinw |10| Stress |11| Xateain

[16] Includes contrast (CnTt) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial bordet

Previoualy cleared via k100931

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						Mode of O	Mode of Operations			
Clinical Application	В	×	PWD	CWD	Color	Amplitude	Combined	Color Velocity	Наттопіс	Other (specify)
	- "				Doppler	Doppler (PD)	<u>₹</u>	Mapping (TVM)	Imaging (TEI)	;
Ophthalmic										
Fetal	1	Ь	Δ.		a.	Ь	ф		Ы	6, 8, 9, 12, 13
Abdominal	Ъ	Ь	Δ.		e.	a.	ā.		a.	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	ч	_	۵.		4	۵	4		۵	6, 8, 9, 12, 13
Small Organ [1]	ф	Ь	۵		Ь	4	۵		۵	6, 8, 9, 12, 13, 14
Neonatal Cephalic	ď	а	ď		٩	4	4		Ь	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]	d	Ь	Ь		Ь	Ь	e.		4	6,8, 9, 10, 12, 12, 13
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular					-			-		
Peripheral Vascular	Ь	Ь	ď		Ь	4	ī.		a,	6, 8, 9, 12, 13
Laparoscopic						ļ				
Musculo-skeletal Conventional	d	a,	ፈ		ф	ď	e.		d,	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	Д,	۵	۵.		D.	<u>a.</u>	۵		a.	6, 8, 9, 12, 13, 14
Other (Urological)	ч	Ь	Ы		Ь	4	_		_	6, 8, 9, 12, 13
N: New indication; P. Previously cleared by FDA; E:Aided under Appendix E	eared by F	DA; E:Adda	ed under Ap	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiae is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] Vpan

|9| XView |10| Stress

[11] Strain

[12] Compound Imaging (Mview) [13] Trapezoidal View (TP-View)

[14] Elastography

Previously cleared via k100931

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						Mode of	Mode of Operations			
Clinical Application	В	W	QMA	смр	Color Doppler	Amplitude Doppler (PD)	Amplitude Combined Doppler [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	d	Ь	Ь		۵	Ь	۵		ь	6, 8, 9, 12, 13
Abdominal	d	Ь	d		Ь	Ь	а.		ů,	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ы	٩.	Ь		a,	Δ.	c.		_	6, 8, 9, 12, 13
Small Organ [1]	d	Ь	Ь		Ь	ā.	α,		۵	6, 8, 9, 12, 13, 14
Neonatal Cephalic	ď	d	d		Ь	Ь	d.		a	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	ď	Ь	d		Ь	۵	4		Ē.	6, 8, 9, 12, 13
Laparoscopic									-	
Musculo-skeletal Conventional	d.	Ь	۵		а	4	4		d	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	d	ď	d		ы	Ь	α,		ď	6, 8, 9, 12, 13, 14
Other (Urological)	ч	Ь	d		Ъ	Ь	Ь		Ь	6, 8, 9, 12, 13
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N: New indication; P. Freviously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skrietal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+Pl)

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GE [9]

|8| Vpan [9] XView

[12] Compound Imaging (Mview)

[13] Trapezoidal View (TP-View.) [14] Elastography

Previously cleared via k100931

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			i			Mode of Operations	erations			
Clinical Application	В	W	амч	CWD	Color	Amplitude	Amplitude Combined	Color Velocity	Harmonic	Other (specify)
					Doppler	Doppler (PD)	<u>+</u>	Mapping (IVM)	Imaging (TEI)	
Ophthalmic					•					
Fetal	Δ,	ď	_		Ь	d	a.		۵.	6, 8, 9, 12, 13
Abdominal	а.	ъ.	۵.		Ь	a.	Ы		ď	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	۵.	۵.	-		Ь	۵	<u>a</u>		a	6, 8, 9, 12, 13
Small Organ [1]	Δ.	۵.	4		Ъ	۵	۵		۵	6, 8, 9, 12, 13, 14
Neonatal Cephalic	d,	Ь	ь		4	۵	Ь		۵	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	4	ď	d		Ь	d,	d		D.	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	Δ.	a.	d		Р.	d	d		a.	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	d.	ď	d		Ь	Ь	۵.		۵	6, 8, 9, 12, 13, 14
Other [Urological]	Ъ	ď	ч		Ь	Ь	Ь		4	6, 8, 9, 12, 13
N: New indication; P. Previously cleared by FDA; E:Added under Appendix E	leared by F	DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletai - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

dE [9]

[8] Vpan [9] XView [12] Compound Imaging (Mview) [13] Trapezoidal View (TP-View) [14] Elastography

Previously cleared via k100931

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

K102152 516K

LA523

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode of Operations	<u>perations</u>			
Clinical Application	. 8	M	OMd	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other (specify)
			-		Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	Ы	ď	Ь		Δ.	۵.	Д		ď.	6, 8, 9, 12, 13
Abdominal .	ď	Ь	ď		4	, a.	ሲ		a.	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	d	ď	ч		Δ.	a,	Ы	ч	a.	6, 8, 9, 12, 13
Small Organ [1]	А	Ъ	ď		۵	a.	<u>.</u>	٠.	۵	6, 8, 9, 12, 13, 14
Neonatal Cephalic	Ь	۵	4		Ь	4	a		۵	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]	Ą	А	d		a,	۵	д		۵	5, 8, 9, 10, 12, 12, 13
Transesuphageal (Cardiac)										
Transcsuphageal (Non Cardiac)										
Transrectal										
Transvaginal										
Trunsprethral										
Intravascular										
Peripheral Vascular	Ь	Ь	Ь		Д	e.	4	Ь	۵	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	Ы	4	d.		4	a.	Ь	Δ.	۵,	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	Ъ	4	<u>α</u>		α.	_	4	Δ.	e.	6, 8, 9, 12, 13, 14
Other (Urological)	Ь.	d.	Ь		G.	۵	۵.		۵	6, 8, 9, 12, 13
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	(cared by	DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

GE [9]

(B) Vpan

[10] Stress [9] XView

[12] Compound Imaging (Mview) [13] Trapezoidal View (TP-View) [14] Elastography [11] Strain

51001H 5152

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics

Previously cleared via k100931

LA532

						Mode of Operations	rations			
Clinical Application	В	Σ	GWG	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other (specify)
		·			Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	4	a.	_		а	Ь	4		Ь	6, 8, 9, 12, 13
Abdomined	Ь	Ы	۵		_	а	d,		Ь	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ь	Ь	4		Ь	Ь	2	4	d.	6, 8, 9, 12, 13
Small Organ [1]	Ь	d	4		Ь	4	_	4	а.	6, 8, 9, 12, 13
Neonatal Cephalic	d	d	Ь		d	4	<u>a</u> .		a.	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ь	P		Ь	ы	£.	۵	d	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	ф	d	d		a.	a.	d		a.	6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	Ч	d	Ь		ď	Ь	n,		a	6, 8, 9, 12, 13
Other (Urological)	d	d	Ь		Ъ	Ь	ų		ď	6, 8, 9, 12, 13
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by	FDA; E:Add	led under A	sppendix E	6.3					

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

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H103152

510K

(6) 3D

[8] Vpan [9] XView

[12] Compound Imaging (Mview) [13] Trapezoidal View (TP-View)

Previously cleared via k091009

						Mode of Operations	erations			
Clinical Application	В	W	DWP	CWD	Color	Amplitude Combined	Combined	Color Velocity	Harmonic	Other (specify)
	•				Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	[maging (TE!)	
Ophthalmic										
Fetal	4	d	Ь		Ь	۵	Ь		۵.	6, 8, 9, 12, 13
Abdominal	д	۵.	Ь		۵	Ь	Ь		G.	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	۵	۵	۵.		Ы	_	۵.		ď	6, 8, 9, 12, 13
Small Organ [1]	Ь	d	a.		Ь	۵.	_		Ы	6, 8, 9, 12, 13
Neonatal Cephalic	Ь	d	Ь		Ь	۵			4	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardinc)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	d	Ь		Ь	d	c.		ď	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional [3]	Д	d	ů,		4	ď	d		ď	6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	ч	ŋ.	ů,		۵.	d,	<u>a</u>		۵.	6, 8, 9, 12, 13
Other (Urological)	Ъ	Ь	Ъ		Ы	Ь	Ь		å,	6, 8, 9, 12, 13
M. Manning Minnessen B. Bennings and	100.00	har DDA : D.A.L.	J-d sandon							

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+Cj:M+PD

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K102152

510K

[6] 3D [8] Vpan [9] XView [12] Compound Imaging (Mview) [13] Trapezoidal View (PP-View)

Previously cleared via k100931

C5-2R13

						Mode of Operations	perations			
Clinical Application	я	W	PWD	CWD	Color	Amplitude	Amplitude Combined	Color Velocity	Наттопіс	Other (specify)
				,,	Doppler	Doppler (PD)	₹	Mapping (TVM)	(maging (TEI)	•
Ophthalmir										
Fetal	_	_	_		۵	d	d		a,	5, 6, 8, 9, 12
Abdominal	Ь	۵	۵		Ь	Ы	_		n.	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological			_							
Pediatric	4	۵.	ч		4	۵	4		a.	5, 6, 8, 9, 12
Small Organ [1]	Ь	ь	4		ч	۵	4		d.	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P.	d	Ъ		А	ď	d.		В	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophagnal (Non Cardiac)										
Transfectal	L									
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	ď	d		ч	А	r.		۵	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	а.	d	а		d.	a.	a.		ů.	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	£.	<u>a</u>	4		d	۵.	Δ.		n,	5, 6, 8, 9, 12
Other (Urological)	Ь	d	Ь		Ь	۵	ď		Ь	5, 6, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by F	'DA; E:Add	ed under A	ppendix E						

[1] Smail Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

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H103152

510K

[6] 3D

[8] Vpan [9] XView

[10] Stress [11] Xstrain [12] Compound Imaging (Mview)

Previously cleared via k100931

CA123

						Mode of Operations	perations			
Clinical Application	Н	M	PWD	cwD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	۵	a,	_		a.	Ь	d.		А	5, 6, 8, 9, 12
Abdominal	_	а	_		d.	_	Д.	d.	Ь	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological							i	,		
Pediatric	۵.	а.	<u>.</u>		4	Ь	<u>.</u>	4		5, 6, 8, 9, 12
Small Organ [1]	Ь	Ь	۵		Ъ	4	Ь	•	۵	5, 6, 8, 9, 12
Neonatal Cephalic	ď	Ь	4		۵,	۵.	а	4	۵	5, 6, 8, 9, 12
Adult Cephalic										
Cardiac [2]	ď	Ь	d		ī.	Ы	1	Ь	d.	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
							_			
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	d	ď	Ь		ф	ď.	d.	4	4	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	۵	а.	ā.		4	<u>a</u> .	Δ.		ρ,	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	d.	۵	2		e.	۵.	Ē,		4	5, 6, 8, 9, 12
Other (Urological)										
N: New indication; P. Previously cleared by FDA: E. Added under Appendix E	eared by F	DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

|4| Combined modes are: B+M+PW+CFM+PD

|5| Compass M-Mode (CMM)

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K103152

510K

(e) 3D

[8] Vpan [9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

Previously cleared via k100931

CA421

						Mode of Operations	erations			
Clinical Application	æ	∑	PWD	cwp	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	_	4	_		d.	۵	۵	4	4	5, 6, 8, 9, 12
Abdominal	d.	a.	4		d	Ь	_		Ь	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	۵.	р.,	_		-	Ь	۵.	a.	a,	5, 6, 8, 9, 12
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										İ
Cardiac [2]										
Transesophageal (Cardinc)										
Transesophageal (Non Cardiae)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ъ	Ь		۵	Ь	a.	۵	d	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	ď	ď	ď		۵.	a.	<u>a</u>		۵.	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	۵.	d	D.		۵.	_	_		Δ.	5, 6, 8, 9, 12
Other (Urological)	ď	Ь	r.		Ь	Ь	ы	Ъ	۵.	5, 6, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by F	'DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiae is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

|4| Combined modes are: B+M+PW+CFM+PD |5| Compass M-Mode (CMM) [6| 3D

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102152

[8] Vpan [9] XView [12] Compound Imaging (Mview)

Previously cleared via k091009

CA621

						Mode of Operations	rations			
Clinical Application	В	М	GW4	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other
					Doppler	Doppler (PD)	<u>‡</u>	Mapping (TVM)	Imaging (TEI)	(specify)
Ophthalmic					!					
Fetal	۵	n,	4		Ľ.	r.,	۵۰	4	E.	5, 6, 8, 9, 12
Abdominal	٦	ď	4		Ь	Ы	ď.	ď	4	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	۵	Ь	l b		۵	<u>a.</u>	Ь		۵	5, 6, 8, 9, 12
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transrectal										
Trunsvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	d	d	d		۵	۵	Ь	a.	۵	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional										:
Musculo-skeletal Superficial [3]										
Other (Urological)	Ь	Ь	2		Ь	Ь	Ь	ч	4	5, 6, 8, 9, 12
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N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

|4| Combined modes are: |B+M+PW+CFM+PD

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510K

[5] Compass M-Mode (CMM)

de [9]

[8] Vpan [9] XView

[12] Compound Imaging (Mview)

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Previously cleared via k091009

CA430

						Mode of Operations	perations			
Clinical Application	m	×	PWD	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other (specify)
					Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	d	d	Ь		a.	a.	а		Ь	5, 6, 8, 9, 12
Abdominal	4	Ь	4		_	ı.	4		۵	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	•	۵	Ь		_	Ь	4		Ь	5, 6, 8, 9, 12
Small Organ [1]	Ы	Ъ	Д		ď	4	4		ď	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	d	d	ď		ď	а,	p.		(91) d	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular	1									
Peripheral Vascular	4	d	ď		۵	Ь	۵		-	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]	d	đ	d		Ь	Ь	۵		a.	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	d	Ы	۵	_	C.	Δ.	p.		c.	5, 6, 8, 9, 12
Other (Urological)	Ь	Ь	۵		F	ь	Ь		۵	5, 6, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	Jeared by F	'DA; E.Add	ed under A	pendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

(e) 3D

[8] Vpan [9] XView [10] Stress [11] Xstrain [12] Compound Imaging (Mview)

[16] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics

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Office of In Vitro Diagnostic Device Evaluation and Safety H103152 510K

						Mode of Operations	Perations			
Ciinical Application	g	М	ci wa	CWD	Calor Doppler	Amplitude Combined Doppler [4] (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TE3)	Other (specify)
Ophthalmic										j
Fetal	۵.	D.	D.		۵	Δ,	۵		d.	5, 6, 8, 9, 12
Abdominal	Ы	ы	a.		ď	đ,	d.		d.	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										i
Pediatric	p.	a.	_			d	a,		ď	5, 6, 8, 9, 12
Small Organ [1]	d.	d	<u>.</u>		e.	۵.			d	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	ď	4	4		c.	Ч	L		P (16)	5, 6, 8, 9, 10, 11, 12
Transcsophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transcetal										
Transvaginal										
Transurethral										i
Intravascular										
Peripheral Vascular	Ь	d	ď		4	д	ı,		ч	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	ď	А	ά.		۵.	L	<u>-</u>		Δ,	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	Ь	ď	d		a.	۵.	<u>.</u>		a.	5, 6, 8, 9, 12
Other (Urological)	Ь	Ъ	٦		ь	а	۵		. а	5, 6, 8, 9, 12
N. M 1	1 1 1 1 1	F-1-4-0-14-03		ĺ						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Prdiatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510X

[6] 3D [8] Vpan [9] XView

110] Stress

111 Xstrain

[12] Compound Imaging (Mview)

[16] Includes contrast (CnTl) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocratilal border

Previously cleared via k100931

						Mode of Operations	perations			
Clinical Application	В	W	σMd	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	ь	d	Δ.		ы	d.	۵.		a.	5, 6, 8, 9, 12
Abdominal	Ь	ď	Ь		a.	а	ы		d	5, 6, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	Ъ	α,	d		а	р.	a.		۵	5, 6, 8, 9, 12
Small Organ [1]	Ь	a.	а		a.	a.	a.		_	5, 6, 8, 9, 12
Neonatal Cephalic										
Adult Cephalic										
Cardiae [2]	d	ď	d.		۵	۵	4		<u>a</u> .	5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardine)										
Transfectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Р	ā.	Ь		e.	D.	2,	-	£.	5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	а	۵.	а,		d.	а,	a.		۵	5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	Р	d	Ъ		۵.	D.	a.		Δ.	5, 6, 8, 9, 12
Other (Urological)	Ь	Ь	ď		ы	а	4		ď.	5, 6, 8, 9, 12
N: New indication: P: Previously cleared by FDA: E:Added under Appendix E	Fared by F	DA: E:Adde	ed under A	pendix E						

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeietal - Nerve Block [4] Combined modes are: B+M+PW+CFM+PD

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510K

[5] Compass M-Mode (CMM) [6] 3D

| B| Vpan | 9| XView | 10| Stress | 11| Xstrain | 12| Compound Imaging (Mview)

Previously cleared via k100931

2CW

					a	Mode of Operations	ations			
Clinical Application	В	×	DWD	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other
					Doppler	Doppler (PD)	4	Mapping (TVM)	Imaging (TEI)	(specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										:
Intraoperative Neurological										
Pediatric										•
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				۵.		ļ				
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transfectal										
Transvaginal										
Transurethral								3		
Intravascular										
Peripheral Vascular				Ь						
Laparoscopic										
Musculo-skeletal Conventional		•								
Musculo-skeletal Superficial [3]							:			
Other (Urological)										
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by l	FDA; E:Add	led under A	ppendix E			1			

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

Previously cleared via k100931

SCW

PWD CWD Color Amplitude Contined Color Velocity						=	Mode of Operations	ations			
Doppler Doppler [4] Mapping (TVM)	Clinical Application	m	W	DWD	GMD	Color		Combined	Color Velocity	Нагтопіс	Other
						Doppler		[4]	Mapping (TVM)	Imaging (TEI)	(specify)
	Ophthalmic										
	Fetal										
	Abdominal	,									
	Intraoperative (Abdominal)										
	Intraoperative Neurological										
	Pediatric										
	Small Organ [1]										
	Neonatal Cephalic										
	Adult Cephalic										
	Cardiac [2]										
	Transcsophageal (Cardiac)					;					
	Transcsophageal (Non Cardiac)										
	Transrectal				T						
	Transvaginal										
	Transurethral										
	Intravascular										
Laparoscopic Musculo-skeletal Conventional [3] Musculo-skeletal Superficial [3]	Peripheral Vascular				a.						
Musculo-skeletal Conventional [3] Musculo-skeletal Superficial [3]	Laparoscopic										
Musculo-skeletal Superficial [3]	Musculo-skeletal Conventional										
Other Histories II	Musculo-skeletal Superficial [3]										
Other (Dimogram)	Other (Urological)										
	The second secon										

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve

Block

[4] Combined modes are:

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					Æ!	Mode of Operations	ations			
Clinical Application	8	¥	PWD	CWD	Color	Amplitude	Combined	Color Velocity	Harmonic	Other
					Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	(specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				Ь						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]								-		
Other (Urological)										
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	sleared by	FDA; E:Ado	ded under /	Appendix I	(+1					

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:

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Previously cleared via k100931

EC123

						Mode of Operations	rations			
Clinical Application	В	M	БWD	CWD	Color Doppler	Amplitude Combined Doppler [4]	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	d	Ь	ď		Ь	d	d	ď.	Ь	5, 6, 8, 9, 12
Abdominal										
intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	d	Ь	_ _		P	d	4	Ъ	ч	5, 6, 8, 9, 12
Transvaginal	ď	Ь	4		ą.	d	d	Р	d	5, 6, 8, 9, 12
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional				٠,						
Musculo-skeletal Superficial [3]										
Other (Urological)	Ь	Ь	Ь		Ь	d	d	Р	Ь	5, 6, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by I	²DA; E:Add	led under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

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[5] Compass M-Mode (CMM)

[6] 3D

[8] Vpan [9] XView [12] Compound Imaging (Mview)

Previously cleared via k100931

						Mode of C	Mode of Operations			
Clinical Application	В	Σ	OWP	CWD	Color	Amplitude	Amplitude Combined	Color Velocity	Harmonic	Other (specify)
					Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	d	4	d		d.	d	А	d	Ь	5, 6, 8, 9, 12
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatríc										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiae)										
Transrectal	1	e.	Ь		<u>.</u>	D.,	G.	ď	٩	5, 6, 8, 9, 12, 14
Transvaginal	<u>.</u>	Ь	d I		٩	e,	ď	ф	Ь	5, 6, 8, 9, 12
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	4	d	Ь		ъ	Ь	Ь	ч	d	5, 6, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	rleared by	FDA; E:Add	ded under A	Appendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compass M-Mode (CMM)

(e] 3D

ki Vpan 19] XView 112] Compound Imaging (Mview) (14] Elastography

Previously cleared via k100931

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						Mode of Operations	perations			
Clinical Application	В	W	QM4	CWD	Color	Amplitude Combined	Combined	Harmonic	Наттопіс	Other (specify)
					Doppler	Doppler (PD)	Ŧ	Imaging (TEI)	Imaging (TEI)	•
Ophthalmic										-
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	a.	ď	Ь		Ы	ρ.,	Ь	Ь	Ь	5, 6, 8, 9, 12, 13, 14
Transvaginal	ч	ч	Ь		Ы	Δ.	ı.		4	5, 6, 8, 9, 12, 13, 14
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)	ч	Ь	Ь		Ь	Ь	a.	4	ď	5, 6, 8, 9, 12, 13
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by	FDA; E:Ad	ded under	Appendix	ы					

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric [3] Musculo Skrietal - Nerve

[4] Combined modes are: B+M+PW+CFM+PD Block

[5] Compass M-Mode (CMM)

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[8] Vpan [9] XView (6) 3D

[12] Compound Imaging (Myiew) [13] Trapezoidal view (TPView)

[14] Elastography

Previously cleared via k100931

BE1123

						Mode of Operations	erations			
Clinical Application	В	М	DWD	CWD	Color	Amplitude Combined	Combined	Color Velocity	Harmonic	Other (specify)
					Doppler	Doppler (PD)	4.	Mapping (TVM)	Imaging (TEI)	
Ophthalmic					i					
Fetal	Ь	d	ď		ď	Ь	а	Ь	ď	5, 6, 7, 8, 9, 12
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	۵	ď	l a		_	4	4	d.	Ы	5, 6, 7, 8, 9, 12
Transvaginal	۵.	<u>.</u>	Ъ		4	Ы	۵	Ь	۵	5, 6, 7, 8, 9, 12
Transurethral										
Intravascular							ļ -			
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	Ъ	Ь	Р _		А	Ы	a.	Ь	Ь	5, 6, 7, 8, 9, 12
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by 1	FDA; E:Add	led under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

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[5] Compass M-Mode (CMM)

GE [9]

(7) 4D [8] Vpan [9] XView

[12] Compound Imaging (Myew)

Previously cleared via k100931

TEE022

						Mode of	Mode of Operations			
Clinical Application	В	M	QM4	CWD	Color	Amplitude Combined	Combined	Color Velocity	Harmonic	Other (specify)
					Doppier	Loppier (PD)	<u>+</u>	Mapping (JVM)	maging (151)	
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	Ь	Ь	Ь	Ъ	Ь	A	Ъ	Ь	Ь	5, 6, 9, 10, 11
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										•
(8)										
Musculo-skeletal Superficial [3]										
Other (Urological)										
N: Name in districtions D. Bression of a cleaned by EDA . B. Added ander Anneadir E	nered har	PDA-F-Ade	der under	Appeadix	í.					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric [3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+l³W+CFM+PD

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[5] Compass M-Mode (CMM)

[6] 3D [9] XView [10] Stress [11] Xstrain

Previously cleared via k100931

						Mode of Operations	erations	1		
Clinical Application	В	М	OMd	CWD	Color	41	Combined	Color Velocity	Нагтопіс	Other (specify)
			_		Doppler	Doppler (PD)	Œ	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiae [2]										
Transesophageal (Cardiac)	Ь	d	ત] d	Ы	Ь	Ь	Ъ	a,	5, 6, 9, 10, 11
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial [3]										
Other (Urological)										
	ŀ	1	And and and	Annualis	į.					

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[5] Compass M-Mode (CMM) |4| Combined modes are: |B+M+I^W+CFM+PD

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(e) 3D

[9] XView [10] Stress [11] Xstrain

Previously cleared via k100931

IOE323

						Mode of Operations	erations			
Clinical Application	Я	W	GMA	CWD	Color	Amplitude Combined	Combined	Color Velocity	Harmonic	Other (specify)
	-				Doppler	Doppler (PD)	<u>4</u>	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	ď	d	Ь		Ь	ď	d		ď	6, 8, 9, 12, 13
Abdominal	ď	۵	4		Ь	ч	4		£.	6, 8, 9, 12, 13
Intraoperative (Abdominal)	Ь	Ь	Ь		4	4	Ь		d.	6, 8, 9, 12, 13
Intraoperative Neurological										
Pediatric	ф	Ь	_		Ь	ď	Ы		D.	6, 8, 9, 12, 13
Small Organ [1]	Ъ	_	۵		Ь	d	Ы		۵.	6, 8, 9, 12, 13, 14
Neonatal Cephalic	Ь	Ы	Ь		۵	ď	4		a,	6, 8, 9, 12, 13
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiae)			į							
Transesophageal (Non Cardiac)									•	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	ď	Ь		Ь	d	Ь		d	6, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	e.	d.	a,		ط	ď	a.		a.	6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	e,	a	A.		d	ď	a.		Δ.	6, 8, 9, 12, 13
Other (Urological)	d	ď	ь		Ь	Ь	А		Ы	6, 8, 9, 12, 13
N: New indication; P. Previously cleared by FDA; E:Added under Appendix E	leared by I	'DA; E:Add	ed under A	3 xipuadd						

[1] Small Organs includes Breast, Thyroid and Testicles

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[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

QE [9]

[8] Vpan

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[9] XView [12] Compound Imaging (Mview) [13] Trapezoidal View [FP-View]

[14] Elastography

Previously cleared via k100931

						Mode of Operations	erations			
Clinical Application	В	W	PWD	CWD	Color	Amplitude	Combined	Color Velocity		Other (specify)
					Doppler	Doppler (PD)	Ŧ	Mapping (TVM)	Imaging (TEI)	
Ophthalmic										
Fetal	Ы	Ь	Ь		Ь	4	d		Ь	6, 8, 9, 12, 13
Abdominal	۵	4	d		d	Ь	d		Ь	6, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E.	۵	Ы		. 4	۵	d		۵	6, 8, 9, 12, 13
Small Organ [1]	a.	Ь	Ь		ď	a.	A.		Ь	6, 8, 9, 12, 13
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvagnal										
Transurethral										
Intravascular										
Peripheral Vascular	۵	Ь	Ь		Ь	ь	4		Ы	6, 8, 9, 12, 13
Laparoscopic	d	ď	ц		ď	ч	4		Ь	6, 8, 9, 12, 13
Musculo-skeletal Conventional										
[c]										
Musculo-skeletal Superficial [3]										
Other (Urological)										
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N: New indication; P. Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

ge [9]

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|8] Урап

[9] XView [12] Compound Imaging (Mview) [13] Trapezoidal View (TP-View)

Previously cleared via k100931

Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonir Imaging (TEI)	Other (specify)
Ophthalmic								:		
Fetal	۵	_	_		d	۵	Ь	ď	Ь	5, 6, 7, 8, 9, 12
Abdominal	4	_	_		d	А	a	ď	ď	5, 6, 7, 8, 9, 12
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	_	۵.	_		Ь	Ь	d	d	đ.	5, 6, 7, 8, 9, 12
Small Organ [1]	_	а.	Ь		ь	Ь	Ы		Р.	5, 6, 7, 8, 9, 12
Neonatal Cephabe										
Adult Cephalic										
Cardiac [2]	Ь	А	ď		d	ч	Ь		Ь	5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transveginel										
Transurethm										
Intravaxular										
Peripheral Vascular	Ь	Ы	ď		Ъ	Ъ	Ъ	Ъ	Ь	5, 6, 7, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional	۵	ů.	d		ď	ď	a.		d.	5, 6, 7, 8, 9, 12
Musculo-skeletal Superficial [3]	a.	Δ,	۵		а	۵	a,		a.	5, 6, 7, 8, 9, 12
Other (Urological)	a.	۵	۵		Ь	۵	ď	Ъ	Ь	5, 6, 7, 8, 9, 12

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E.

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[2] Cardiac is Adult and Pediatric

|4| Combined modes are: B+M+PW+CFM+PD |5| Compass M-Mode (CMM) |6| 3D |7| 4D

[8] Vpan [9] XView [10] Stress

[11] Xistrain

[12] Compound Imaging [Mview]

Previously cleared via k100931

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BL433

						Mode of Operations	perations			
Clinical Application	E	M	QMd	смр	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	4	Ь	d		Ь	d	d		<u>.</u>	6, 7, 8, 9, 12, 13
Abdominal	Ь	4	d.		Ь	Ь	Ь		4	6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	_	۵	a		а	Ь	d		۵	6, 7, 8, 9, 12, 13
Small Organ [1]	_	۵	Δ,		Ь	d	ď		۵	6, 7, 8, 9, 12, 13
Neonatal Cephalic	-	4	۵.		d	d	ď		а,	6, 7, 8, 9, 12, 13
Adult Cephalic										
Cardine [2]										
Transesophageal (Cardiae)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	Ь	Ъ	4		Ъ	d	Ь		Ь	6, 7, 8, 9, 12, 13
Laparoscopic										
Musculo-skeletal Conventional	ď	<u>a</u> ,	۵.		a.	ď	Δ.		e.	6, 7, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	۵	۵.	۵.		Ь	d	۵		а.	6, 7, 8, 9, 12, 13
Other (Urological)	d	Ь	d		۵	-d	۵		Ь	6, 7, 8, 9, 12, 13
N: New indication; P: Previously cleared by FDA; E:Added under Appendix E	leared by F	'DA; E:Add	ed under A	ppendix E						

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

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[4] Combined modes are: B+M+PW+CFM+PD

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GE [9]

[7] 4D

WaiVX [9] |8] Урап

[12] Compound Imaging (Mview) [13] Trapezoidal view (TPView)

Previously cleared via k100931